

SPL ER/DL Team

April 11, 2012

Minutes

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

Chair for this meeting: Pat Cowall

1. Active ingredients and active moieties:

- FDA is starting an effort to clean up the active ingredients and moieties in the SPL. The SPL resources page now has a listing of correct active moieties for each active ingredient, with appropriate UNII's. Pat forwarded an email from Lonnie about this today.
- Do we want to hear a discussion on what an active moiety? Yes. Pat and Jessica to arrange for one of the upcoming er/dl meetings
- Side question: Is the strength of the drug product always related to either the active ingredient or the active moiety? No. It depends on the product. This is specified on the carton/container labeling and in the USPI.
- Basis of strength could also relate to the reference compound. You may also have to include this as a compound in the drug product data elements section. .

2. New SPL Stylesheet:

- DLDE: Delete 3rd column for multilevel packaging
- We don't see RED anymore. (This was only seen if you use IE version 7.0 or greater.)

3. Is the FDA ready for dietary supplements to be submitted and are there any instructions as to how to do so (LOINC's to use, content of labeling to include)? -- Howard

- There is a new terminology update – they now have a marketing category for dietary supplements.
- At this time, these do not have to be either approved or drug listed.
- Lonnie: FDA is ready to accept dietary supplement SPL files.
- Lonnie: The submitter should know which content of labeling section headers to use for these types of documents.
- Marcia: These are covered in the regs. They should have supplement facts which are similar to drug facts on OTC. There is no FDA pre-market approval necessary. There are guidelines to follow.
- What section headings should we use? Should they use the OTC equivalents or use unclassified. Howard will check into this and get back to us.
- Will these be posted to Dailymed? Howard to followup.

4. Can the FDA in on the SPL page, under terminology lists, a "Recent Changes" file that highlights the latest set of terminology changes, with some documentation for each change (like "Establishment De-registration is added as a document type, use it when")-- Howard

- Lonnie: We are not going to add a "recent changes file," etc... to denote new term additions.

5. When is Establishment De-registration used? -- Howard

- The intent of the "out of business" file is when they go out of business.
- Companies are hesitant to say they are "out of business;" when they only want to say that they will no longer supply the US market.
- Deregistration file may not be operational yet.

- What do you do if you are trying to combine multiple DER files into one file for the parent company? **Talk to Lonnie about how to best to this**

6. Advanced SPL training

- How to register? Go to SPL resources page....look for training....list. Send Lonnie an email
- We will post the slide to the WIKI.

7. Update to the labels.fda.gov website- search by both product and company name

- To assist users of the labels.fda.gov (<http://labels.fda.gov/>) website locate a specific label by reducing the amount of labels returned in the query results, the labels.fda.gov website has been updated to include a query which will permit the search of a label by both product and company name.
- The hyperlink to this new query web page named "Proprietary Name and Company" is located on the labels.fda.gov's home page.

8. On Lonnie's call on Monday, he said that FDA is thinking about deprecating the Drug Establishment Registration "no change" file—because they have no way of checking the DUNS numbers.